

REMARKS

The Office Action mailed on September 10, 2010, has been reviewed and the comments of the Examiner carefully considered. Claims 9, 10, 17, 19 and 20 are currently pending and under consideration.

Rejection Under 35 U.S.C. § 103(a)

Claims 9, 10, 17, 19 and 20 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over Okajima (U.S. Patent No. 4,389,523) in view of Michaeli (U.S. Patent No. 4,912,093). The Examiner is of the view that this combination of references would motivate the skilled artisan to arrive at the claimed invention. Applicants respectfully disagree with the rejection for the following reasons.

As a preliminary matter, Applicants note that the claims are directed to compositions having, on each saccharide residue of the synthetic sulfated polysaccharide, from about 3 to about 4 sulfate groups that were converted from hydroxyl groups.

The test which must be met for a reference or a combination of references to establish obviousness has not been satisfied in the instant matter. The MPEP states, in relevant part, the proper test for obviousness:

Office policy is to follow *Graham v. John Deere Co.* in the consideration and determination of obviousness under 35 U.S.C. § 103 ...

[T]he four factual inquiries enunciated therein as a background for determining obviousness are as follows:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and
- (D) Evaluating evidence of secondary considerations. (MPEP § 2141).

When applying 35 U.S.C. § 103, the following tenets of patent law must be followed: 1) the claimed invention must be considered as a whole; 2) the references must be considered as a whole; 3) the references must be viewed without the benefit of impermissible hindsight vision

afforded by the claimed invention; and 4) reasonable expectation of success is the standard with which obviousness is determined. MPEP § 2141 II.

Applicants respectfully submit that the reading of the references, and of Okajima in particular, is incorrect in view of the requirements of 35 U.S.C. § 103, described above.

Okajima teaches, at best, keeping the degree of sulfation within a very narrow range of values, in particular, 0.8 to 2.6 (see column 3, lines 41-44; “The cellulose sulfate salt of the present invention has a total average substitution degree <<F>> of from 0.8 to 2.6.”). Furthermore, Okajima emphasizes the advantages of keeping the sulfation degree (“<<F>>”) below 2.6 (e.g., see column 4, lines 1-18; “However, in the range of 1.5<<F>><2.4, if the value <<f.sub.2>> is about 1.00, the anti-coagulating property is substantially constant and this anti-coagulating property is stable even if the cellulose sulfate salt is stored for a long time. Also from this fact, it is preferred that the value <<F>> be in the range of 1.5<<F>><2.4”).

It is alleged in the Office Action that there is some overlap between 2.6 and the “about 3” value in Applicants’ claims. Applicants respectfully submit that such a teaching cannot be found in Okajima. For example, in column 5, Okajima teaches a “Process II” for preparation of a composition having <<F>> of “about 3” (see lines 40-50). However, Okajima explicitly states that such a preparation is not desirable. Specifically, Okajima states that “[T]he process II is disadvantageous in that the stability of the obtained cellulose sulfate salt with the lapse of time is not satisfactory and also in that if the sulfuric acid substituent is cut off by some means or other, a cellulose sulfate salt satisfying the requirement that the value <<f.sub.2>> is largest among the values <<f.sub.2>>, <<f.sub.3>> and <<f.sub.6>> cannot be obtained. Moreover, this process is not suitable for the production of a medicine, because chlorosulfuric acid having a high toxicity is used.”

In other words, Okajima specifically teaches that a compound with a degree of sulfation of “about 3” is not desirable. Therefore, Okajima explicitly and clearly teaches away from Applicants’ claimed invention, and therefore would not be read by one of skill in the art to teach or even suggest the presently-pending claims. Put another way, Okajima teaches the skilled artisan that it is necessary to prepare a compound that has a maximum degree of sulfation of 2.6, provided other factors are met, and that the prepared compound should avoid degrees of sulfation of “about 3.”

Moreover, Okajima teaches that compounds of the Okajima invention are influenced by molecular weight and viscosity changes, and that such changes would influence the fundus membrane permeability of Okajima's cellulosic sulfate salts (see column 3, lines 8-12). Okajima also teaches that the compounds are dissolved, dialyzed, precipitated and dried before use (see Abstract). These teachings are in contrast to the preparation of wound dressings comprising a synthetic sulfated polysaccharide as presently claimed.

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). See MPEP 2141.02. Applicants note that Okajima, as set forth above, teaches away from the presently-claimed invention. When the reference is read in its entirety, for all it fairly teaches, the skilled artisan could only find motivation to minimize the degree of sulfation, or at best, to keep the degree of sulfation in a range below that set forth in the presently-pending claims.

The Michaeli reference does not cure the deficiencies of the Okajima reference. In fact, the Michaeli reference does not address degree of sulfation in any manner, and therefore, would not be considered by one of skill in the art to provide any guidance whatsoever regarding the idea of preparing a sulfated polysaccharide having any particular degree of sulfation, for any reason.

MPEP 2141 requires that "When making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness." (Emphasis added). Applicants respectfully submit that the conclusions set forth in the Office Action do not meet this burden, because the necessary facts and understandings of one of skill in the art are not pointed out with any particularity. In other words, the Office Action does not provide any reasoning to show a nexus between the references cited and the presently-pending claims, particularly when the teachings of the combined references teach away from the presently-pending claims.

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Applicants note once again that support for the claimed range of “about 3 to about 4” can be found throughout the specification. The skilled artisan is adequately apprised of the meaning of a degree of sulfation of “about 3”, for example. There is abundant direction in the specification as to how the skilled artisan would measure the extent of sulfation of any given molecule. MPEP 2173.05(b) provides that “The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph.” Additionally, the MPEP sets forth that “In determining the range encompassed by the term “about”, one must consider the context of the term as it is used in the specification and claims of the application.”. The context of the term in the instant application is clear to the skilled artisan.

As neither Okajima nor Michaeli, taken alone or in combination with one another, teaches or even discloses the presently-claimed invention, Applicants submit that the combination of references does not render the pending claims obvious. The combination of references does not provide the skilled artisan with any suggestion or motivation to arrive at the claimed invention, and therefore, the combination of references provides no reasonable expectation of success in arriving at the claimed invention. Applicants respectfully request withdrawal of the rejection of claims 9, 10, 17, 19 and 20 under 35 U.S.C. § 103(a).

Conclusion

Applicants respectfully submit that the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 963-5809 to clarify any unresolved issues raised by this response.

The Director is hereby authorized to charge/credit Deposit Account No. **50-0310** (Billing No. 101713-5025) for any other required fees, deficiencies or overpayments in connection with this Response.

Respectfully submitted,

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